APR 2 3 2004

Preview® Treatment Planning Software
Summary of Safety and Effectiveness

Submitter Name:	Medical Media Systems, Inc K040852
Submitter Address:	12 Commerce Avenue West Lebanon, NH 03784
Contact Person:	William F. Greenrose Senior Vice President
Phone Number: Fax Number:	603-298-5509 x 303 603-298-5055
Date Prepared:	April 1, 2004
Device Trade Name:	Preview® Treatment Planning Software
Classification Name, Number & Pro Code:	System, Image Processing, Radiological (21 CFR 892.2050; LLZ)
Predicate Device:	Preview™ Surgery Planning Software, by Medical Media Systems, Inc.
Device Description and Statement of Intended Use	The Preview® Treatment Planning Software is intended to provide accurate, alternative two-dimensional images, as well as three-dimensional models, of patient specific anatomy from existing two-dimensional scan data of organs and tissues. The Preview® product offers the physician the capability to view existing scan data in a format that is more user friendly, and thus enhances the physician's capability to plan treatment. The Preview® product is not intended to provide medical diagnosis or a recommended treatment approach.
Summary of Technological Characteristics	A table comparing the Preview® Treatment Planning Software to the original Preview™ predicate device is attached.

K040852

Substantial Equivalence Comparison		
Viewing Software	**Modified MMS Preview® Treatment Planning Software**	**Original MMS Preview™ Surgery Planning Software (K# 953616)**
Imaging technique	SSD	SSD
Reformatted 2D images from 2D axial images	Yes	Yes
Sequential viewing of 2D images	Yes	Yes
Random viewing of 2D slices	Yes	Yes
Rendered 3D model	Yes	Yes
Multi-color objects in model	Yes	Yes
2D measurements	Yes	Yes
3D measurements	Yes, generated from 2D images.	Yes, same
Interactive 3D model	Yes	Yes
Rotate model	Yes	Yes
Add 2D image to 3D model	Yes	Yes
Control transparency of objects in model	Yes	Yes
User placed markers in model	Yes. Marks placed in 2D images appear in 3D model.	Yes. Same
Color display, 256 colors from 16.7 million	Yes	Yes
Color	1 to 24 bit color	same
Accept input data from multiple formats (e.g., CT, MRI)	Yes	Yes
Accept input data from multiple vendors	Yes	Yes
Create & save surgical plans	Yes	Yes
Supports mouse & keyboard interface	Yes	Yes
Operating platform	Modeling done at MMS on UNIX. Viewing software run on Macintosh OS or DOS/Windows.	Modeling done on Linux platform. Viewing only on Windows OS.
Capability to link to hospital computer network	Yes	Yes
MSVG feature	Yes	No
'Click-Drag' feature	Yes	No
Standardized Mark and Calculation types	Yes	No
Centerline Tensioning/morphing	Yes	No

2D = 2-Dimensional; 3D = 3-Dimensional; SSD = Surface shaded display; MSVG = Manufacturer Specific Virtual Graft

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 3 2004

Medical Media Systems, Inc.
% Ms. Patsy J. Trisler, J.D., RAC
Regulatory Consultant
5610 Wisconsin Avenue, #304
CHEVY CHASE MD 20815

Re: K040852
Trade/Device Name: Preview® Treatment Planning Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and Communication system
Regulatory Class: II
Product Code: 90 LLZ
Dated: March 30, 2004
Received: April 1, 2004

Dear Ms. Trisler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K040852

Device Name: Preview® Treatment Planning Software

Indications for Use:

The Preview® Treatment Planning Software is intended to provide accurate, alternative two-dimensional images, as well as three-dimensional models, of patient specific anatomy from existing two-dimensional scan data of organs and tissues. The Preview® product offers the physician the capability to view existing scan data in a format that is more user friendly, and thus enhances the physician's capability to plan treatment. The Preview® product is not intended to provide medical diagnosis or a recommended treatment approach.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH; Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)	X	OR	Over-The-Counter Use	

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K040852

(Optional Format 1-2-96)